K033233 1/2

NOV - 5 2003

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: LactoSorb® Tibial L-15 Screw and Washer

Common Name: Non-metallic screw and washer

Classification Name: Screw, Fixation, Bone, Non-Spinal, Non-Metallic (21 CFR 888.3040

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Arthrotek Resorbable No-Profile LactoSorb® L-15 Screw and Washer cleared in 510(k) K021832).

Device Description: The device description of the LactoSorb® Tibial L-15 Screw and Washer is as follows:

- Resorbable screw in varying diameters
- Screw pre-assembled with a washer
- Fixation achieved by sandwiching the soft tissue between the two washers and screwing into the bone
- 85% L-Lactide/15% Glycolide copolymer

Intended Use: The LactoSorb® Tibial L-15 Screw and Washer is indicated for the following procedures:

1. ACL and PCL reconstruction
2. Medial collateral ligament repair
3. Lateral collateral ligament repair
4. Posterior oblique ligament repair
5. Iliotibial band tenodesis reconstruction
6. Patellar ligament and tendon repair

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574.267.8137

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This device is also intended to be used as back-up fixation in ACL reconstruction in conjunction with other marketed devices in order to provide additional fixation strength in instances of questionable bone quality.

Summary of Technologies: The overall design, materials and processing methods are similar to the predicate device

Non-Clinical Testing: Mechanical testing demonstrated pull-out testing comparable to the predicate device.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0578

Re: K033233
Trade Name: LactoSorb® Tibial L-15 Screw and Washer
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC, MAI
Dated: October 1, 2003
Received: October 6, 2003

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

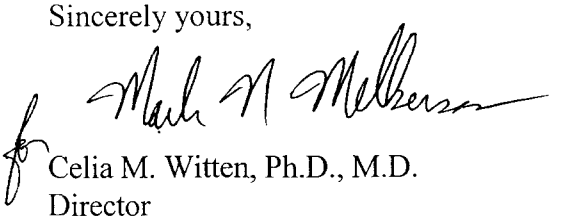
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K033233

DEVICE NAME: LactoSorb® Tibial L-15 Screw and Washer

INDICATIONS FOR USE:

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1. ACL and PCL reconstruction
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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milleen

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033233